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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,200	09/04/2001	Anthony J. Bradshaw	005618.P2306CD	2584

8791 7590 01/17/2007

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EXAMINER	
LACYK, JOHN P	
ART UNIT	**PAPER NUMBER**
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/944,200	BRADSHAW ET AL.	
	Examiner	Art Unit	
	John P. Lacyk	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22,24,26-28,30-59,61-65,67,74 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,24,26-28,30-59,61-65,67,74-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/06 has been entered.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 24, 28, 33, 35, 38-41, 44, 48, 54 and 63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for centering the radiotherapy lumen within the vessel, does not reasonably provide enablement for the longitudinally channeled, fluted, segmented or scalloped balloon being the means for the centering. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. On page 18, the specification states that segments or scallops may be used to permit flow by of blood. There is no teaching of using an inflatable balloon catheter having such segments to center the device or that the segments or scallops are critical to centering the device.

4. Claims 28, 33, 38, 40, 44, 48, 54, 64-65, 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 67 recites language directed to the centering catheter, when deployed, does not dilate the lumen of the duct, however there appears to be no support in the specification directed to such language. The specification does not anywhere discuss the lumen not being dilated when the centering device is deployed.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 28, 30-41, 44-45, 47, 54, 59, 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl (9102312.2) in view of Blackshear, Jr. et al (5,308,356). Weikl discloses a method of treating the wall of a blood vessel by inserting a catheter into the vessel lumen until the balloon is adjacent the target, inflating the balloon to substantially center the radiotherapy lumen (Figure 2), advancing the radioactive source to the treatment region and withdrawing the source after a predetermined interval of time for the therapy. Weikl discloses the claimed method except for allowing perfusion of the blood past the inflated balloon through channels in the balloon. Blackshear, Jr. et al discloses a balloon catheter used for angioplasty and teaches that it is well known to provide a channeled balloon having grooves (36) to allow for the perfusion of blood past

an inflated balloon catheter during the angioplasty procedure. Therefore a modification of the method of Weikl to include a perfusion path through channels in the balloon would have been obvious since this would allow the procedure to continue without being interrupted to deflate the balloon and allow blood to pass. The grooves are considered to also include channels, flutes and scallops, which are similar terms for the same structure. With respect to claims 21, 27, 32 and 59 to select any well known radioactive source with specific radiation dosages would have been obvious to one skilled in the art based upon the its suitability for the intended use. Since different radioactive sources are known to provide different doses and different areas of the body may need specific dose range to select the specific radiation material to provide a specific radiation dosage would have been obvious to one skilled in the art based upon which material would be more suitable for the intended use.

7. Claims 48, 51-53, 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Blackshear, Jr. et al as applied to claims above, and further in view of Van't Hooft et al (4,881,937).

Weikl in view of Blackshear, Jr. et al discloses the claimed method except for the use of an afterloader having a dummy wire to determine the proper placement of the radioactive wire. Van't Hooft et al teaches that it is well known to use such an afterloader having a dummy wire to aid in proper placement of the radioactive source. Therefore a modification of Weikl such that the device is used with an afterloader and dummy wire would have been obvious in view of the teachings of Van't Hooft et al.

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Malinowski et al (5,660,180).

Weikl discloses the claimed invention except for the catheter being inserted or advanced over a guidewire that has previously been inserted. Malinowski et al teaches that it is well known to use the aid of a guidewire for inserting a catheter and the guidewire being inserted first and the balloon catheter being inserted over the guidewire to guide the catheter to the desired area in the body. Therefore a modification of Weikl to use a guidewire to aid in inserting or advancing the catheter of Weikl to the proper place would have been obvious in view of the teachings of Malinowski et al since the use of guidewires to aid in inserting catheters is well known.

9. Claims 19, 21-22, 24, 27, 62-65 and 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Malinowski et al as applied to claims above, and further in view of Blackshear, Jr. e tal.

Blackshear, Jr. et al, as discussed above, teaches the use of a segmented, channeled or scalloped balloon and a modification would have been obvious for the same reasons as discussed above.

10. Claims 20, 26, 42-43, 46, 49-50, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikl in view of Malinowski et al and Blackshear, Jr. et al as applied to claims above, and further in view of Flexmedic article.
Weikl discloses the claimed method except for the guidewire for inserting the radioactive source being made from a super-elastic material. Flexmedics discloses the use of Nitinol which is a well known shape memory alloy that has superelastic properties and teaches that it is well known to use such a material with guidewires. Therefore a modification of Weikl such that the wire used to insert the radioactive source is made from Nitinol would have been obvious since this would have been the mere substitution of one well known guidewire material for another.

11. Applicant's arguments filed 11/29/06 have been fully considered but they are not persuasive. Applicant argues that the specification is enabling for centering the radiotherapy lumen within the vessel and that the rejection under 35 USC 112 first paragraph should be withdrawn. Applicant argues that the claims are actually narrower than the specification and that while the balloon is defined as "inflatable" the specific design of the balloon cannot be read into the generic term "inflatable balloon". However the examiner's position is that the rejection is proper since applicant is arguing that the specific design or shape (segmented, scalloped, or channeled) is critical to centering the device and that the claimed device defines over the prior art because of the prior art cannot center the device because it does not have such a shape. Therefore since this is argued as a critical feature in defining over the prior art the specification must have

proper support for such limitations. While the specification does support an inflatable balloon for centering the source tip it does not support the specific shape being the reason that the device is centered and since it is a critical feature of the device the specification should have support for such a critical feature.

Applicant also argues that the inflated balloon being inflated without dilating the vessel wall is an "inherent feature" of the segmented, scalloped, channeled or fluted balloon. The examiner's position is that whether the vessel is dilated or not is not an inherent feature of the shape but could be dependent on many things including the amount of inflation pressure placed into the balloon, the material that the balloon is made from, whether the balloon has a uniform thickness or varies in different parts of the balloon, etc. Therefore one cannot attribute the prevention of dilating the vessel wall inherently to the shape of the balloon and the specification fails to disclose anything relating to the shape preventing the dilation of the vessel wall or anything at all regarding the vessel wall not being dilated.

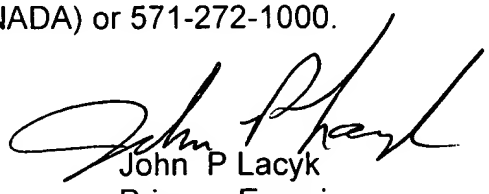
Applicant argues that the prior art rejections are improper because Weikl and Blackshear do not teach the limitation of "without dilating the lumen due to a channeled, fluted, scalloped, or segmented centering balloon". As discussed above Blackshear was used to provide a teaching that it is well known to use what is considered to be a "channeled, scalloped or segmented" balloon. Further in view of applicant's arguments above this would be an inherent feature of such a shape. Therefore the examiner's position is that either this is an inherent feature of the shape in which the prior art would

meet such claim limitations or the feature is not inherent and the written description is not proper as rejection under 35 USC 112 first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John P Lacyk
Primary Examiner
Art Unit 3735

J.P. Lacyk